

REMARKS

Claims 21, 24-32, and 35-39 are pending in this application. Non-elected claims 32 and 35 are withdrawn from consideration by the Examiner. By this Amendment, claims 21, 24, and 35 are amended and claims 23 and 34 are canceled. Support for the amendments to the claims may be found, for example, in the claims as originally filed.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Information Disclosure Statement

An Information Disclosure Statement with Form PTO-1449 was filed on October 23, 2006. The copy of the October 23, 2006 Form PTO-1449 returned with the Office Action indicates that FR 2 609 397 A1 (reference 9) has not been considered. Applicants respectfully submit that the non-consideration of FR 2 609 397 A1 was in error.

In the June 4, 2009 Amendment, Applicants explained why FR 2 609 397 A1 must be considered. Applicants, however, indicated that FR 2 609 309 A1 (reference 12) need not be considered because it was cited in error.¹ However, the two Form PTO-1449's returned with the Office Action indicate that FR 2 609 309 A1 was considered, although it need not be, and the October 23, 2006 Form PTO-1449 indicates that FR 2 609 397 A1 was not considered, although it should have been.

Accordingly, the Examiner is respectfully requested to consider FR 2 609 397 A1, and initial and return to Applicants a copy of the October 23, 2006 Form PTO-1449 indicating that FR 2 609 397 A1 has been considered of record.

¹ FR 2 609 309 A1 is also listed as reference 1 in the November 14, 2006 Information Disclosure Statement.

II. Rejections Under 35 U.S.C. §103

A. Claims 21, 36, and 39

The Office Action rejects claims 21, 36, and 39 under 35 U.S.C. §103(a) as having been obvious over U.S. Patent Application Publication No. 2002/0019431 to Straub et al. ("Straub") and WO 98/47374 A1 to Farmer et al. ("Farmer"). Applicants respectfully traverse the rejection for at least the following reasons.

By this Amendment, claim 21 is amended to be directed to "[a] dermal and/or cosmetic galenic base whose aqueous phase contains polyols consisting of xylitol, mannitol, rhamnose and fructooligosaccharides" (emphasis added). The applied references would not have rendered obvious the claimed base containing the following combination of polyols (in the aqueous phase): (1) xylitol; (2) mannitol; (3) rhamnose; and (4) fructooligosaccharides.

The Office Action asserts that "Straub teaches a topical matrix, in the form of a cream or ointment, for delivery [of] an active ingredient" and that "[t]he matrix includes sugars such as mannitol, xylitol, glucose, and rhamnose." See Office Action at page 3. To the contrary, Straub does not provide an ordinarily skilled artisan with any reason or rationale to select a combination of polyols, much less to select the specific combination of polyols of the claimed galenic base.

Straub is directed to providing a specific drug for treating inflammation--celecoxib--in a porous matrix form so that the dissolution rate of the drug is enhanced when the matrix is contacted with an aqueous medium. See abstract and paragraphs [0005] and [0018]. The porous matrix is made using a process that includes (i) dissolving celecoxib in a volatile solvent to form a drug solution, (ii) combining at least one pore forming agent with the drug solution to form an emulsion, suspension, or second solution, and (iii) removing the volatile solvent and pore forming agent from the emulsion, suspension, or second solution to yield the dry porous matrix of celecoxib. See abstract and paragraphs [0013] and [0018].

Straub discloses that the porous celecoxib matrix "may contain hydrophilic excipients such as water soluble polymers or sugars." See paragraph [0019]. Straub discloses more than 30 "representative" sugars and indicates that mannitol, lactose, sucrose, sorbitol, trehalose, and glucose are preferred. See paragraph [0029]. Nowhere does Straub disclose that the porous celecoxib matrix should include a combination (whether two, three, or all four) of the polyols recited in claim 21. Rather, out of the polyols recited in claim 21, mannitol is the only one that is disclosed as a preferred component of Straub's porous celecoxib matrix.

Additionally, an ordinarily skilled artisan would not understand Straub to generally disclose providing a combination of any of its representative sugars in its celecoxib matrix. Straub names numerous representative sugars (see paragraph [0029]); however, nowhere does Straub disclose that any of such sugars should be provided to the matrix in combination. Instead, the only exemplified celecoxib matrix of Straub includes mannitol as the sole sugar in the matrix. See paragraphs [0062]-[0063].

Thus, Straub does not disclose and would not have rendered obvious a galenic base in which the aqueous phase contains polyols consisting of the combination of (1) xylitol, (2) mannitol, and (3) rhamnose, and an ordinarily skilled artisan would not have had any reason or rationale to select this combination of polyols in view of Straub. The Office Action acknowledges that Straub does not disclose (4) fructooligosaccharides. See Office Action at page 3. The Office Action relies on Farmer for teaching this claim feature. *Id.*

However, an ordinarily skilled artisan would not have combined Straub and Farmer, especially in any manner that would have yielded the claimed galenic base. Farmer is directed to "[c]ompositions including an isolated *Bacillus* species, spores or an extracellular product of *B. coagulans*, suitable for topical application, for inhibiting growth of yeast, fungus, bacteria or Herpes simplex virus." See abstract. Farmer discloses that fructooligosaccharides may be used in combination with *Bacillus* to promote growth of

Bacillus in a manner that replaces undesirable pathogenic microorganisms that cannot use fructooligosaccharides as a food source, such as *Clostridium*, *Staphylococcus*, *Salmonella*, and *E. Coli*. See page 14, line 21 to page 15, line 7.

An ordinarily skilled artisan would not have attempted to modify the celecoxib matrix disclosed by Straub in view of the teachings of Farmer because the respective teachings of Straub and Farmer, as well as the compositions disclosed by both, are entirely unrelated. Straub is directed to providing a specific drug for treating inflammation (celecoxib) in matrix form and Farmer is directed to compositions comprising *Bacillus*--i.e., a type of probiotic bacteria--for inhibiting the growth of yeast, fungus, bacteria or Herpes simplex virus. Thus, the respective compositions are unrelated in that the active ingredient in Straub is a small-molecule drug and the active ingredient in Farmer is a specific genus of beneficial bacteria. They are also directed to treating entirely unrelated conditions in that Straub is directed to treating inflammation and Farmer is directed to inhibiting the growth of yeast, fungus, bacteria or Herpes simplex virus.

Thus, an ordinarily skilled artisan would not have had any reason or rationale to attempt to modify the celecoxib matrix of Straub to include fructooligosaccharides disclosed by Farmer. Additionally, the reason for modifying the celecoxib matrix of Straub to include fructooligosaccharides set forth in the Office Action is flawed. See Office Action at page 4. The Office Action asserts that "[i]t would have been obvious to modify the topical matrix of the primary reference by adding FOS to the compositions, given FOS promotes beneficial bacteria in order to replace undesirable bacteria and pathogenic microorganisms as taught by the secondary reference." However, there is no teaching in Farmer that fructooligosaccharides themselves promote beneficial bacteria. Rather, they must be provided in combination with *Bacillus*. The celecoxib matrix of Straub does not include any beneficial bacteria, let alone *Bacillus*, in which fructooligosaccharides could be provided as a

food source to promote beneficial bacteria. Thus, an ordinarily skilled artisan would not have had any reason or rationale to provide fructooligosaccharides to the celecoxib matrix of Straub because the matrix does not comprise *Bacillus* and there is no need for the matrix to promote the growth of beneficial bacteria.

Moreover, an ordinarily skilled artisan would expect that the additional polyols required by claim 21 might act as less specific food sources that both *Bacillus* and undesired microorganism could utilize. This would destroy any ability of fructooligosaccharides to promote *Bacillus* growth in a manner that replaces undesired microorganisms even if *Bacillus* were present. Thus, at most, an ordinarily skilled artisan would understand Farmer to teach that fructooligosaccharides should be provided without other food sources (i.e. without other sugars) to promote *Bacillus* growth. As acknowledged by the Office Action, "Farmer does not teach the addition of mannitol, xylitol and rhamnose." See Office Action at page 3.

Thus, the applied references would not have rendered obvious the claimed galenic base that contains the following combination of polyols (in the aqueous phase): (1) xylitol; (2) mannitol; (3) rhamnose; and (4) fructooligosaccharides, because the applied references do not set forth any reason or rationale that would have led an ordinarily skilled artisan to provide a combination of polyols in a composition, much less provide any reason or rationale that would have led an ordinarily skilled artisan to select the specific combination of polyols of claim 21.

Additionally, the claimed galenic base achieves unexpected results as a result of it containing the specific combination of polyols (1)-(4), which demonstrates nonobviousness. Particularly, it increases cell viability and reduces skin irritation as compared to prior art compositions. See specification at page 15, line 6 to page 17, line 3 (describing a "Study of the skin tolerance and sensitizing power").

In Applicants' Examples, a first galenic base (RO4FF17) is formulated that does not contain mannitol, xylitol, rhamnose and fructooligosaccharides, representing the closest prior art, and a second galenic base (RO4FF18) is formulated that contains the specific combination of (1) mannitol, (2) xylitol, (3) rhamnose, and (4) fructooligosaccharides. See specification at page 15, line 12 to page 16, line 5. The irritation of the two compositions was measured on the basis of the erythema parameter (including edema) and the desquamation parameter according to the following formula:

$$Z = \frac{\Sigma(\text{erythema+desquamation scores})_{\text{product}} - \Sigma(\text{erythema+desquamation scores})_{\text{control}}}{\text{number of subjects} \times \text{number of readings}}$$

See specification at page 16, lines 20-26. RO4FF18 resulted in a irritation index of 0.00, whereas RO4FF17 resulted in a significantly higher irritation index of 0.05. See specification at page 17, lines 2-3. Therefore, a galenic base containing the combination of (1) mannitol, (2) xylitol, (3) rhamnose, and (4) fructooligosaccharides achieves a significant decrease in skin irritation as compared to a composition that does not comprise this combination of polyols. Thus, the claimed galenic base achieves unexpected results, demonstrating nonobviousness.

For at least these reasons, Straub and Farmer would not have rendered obvious claim 21. Claims 36 and 39 depend from claim 21 and, thus, also would not have been rendered obvious by the applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

B. Claim 23

The Office Action rejects claim 23 under 35 U.S.C. §103(a) as having been obvious over Straub, Farmer, and U.S. Patent No. 5,885,593 to Epstein. By this Amendment, claim

23 is canceled, rendering the rejection moot. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

C. Claims 24, 37, and 38

The Office Action rejects claims 24, 37, and 38 under 35 U.S.C. §103(a) as having been obvious over Straub, Farmer, U.S. Patent No. 6,391,324 to Carson et al. ("Carson"), and U.S. Patent No. 6,017,549 to Knight et al. ("Knight"). Applicants respectfully traverse the rejection.

Claims 24, 37, and 38 depend from claim 21 and, therefore, contain all the features of claim 21. The deficiencies of Straub and Farmer with respect to claim 21 are discussed above. Carson and Knight, which the Office Action applies for the additional features recited in claims 24, 37, and 38, do not cure the deficiencies of Straub and Farmer.

Additionally, Carson discloses cosmetic skin care compositions containing pulegone. See abstract. Carson teaches that pulegone enhances the uptake of endogenous glucose and that the uptake may be further increased by adding an additional ingredient, such as exogenous glucose. See column 4, lines 7-15. There would not have been any reason or rationale to modify the porous celecoxib matrix of Straub to include glucose because the matrix of Straub does not contain pulegone and uptake of endogenous glucose is not desired.

Moreover, Knight discloses an emulsion comprising an irritating agent and at least one non-disruptive emulsifier in which suitable emulsifiers include cetearyl glucoside. See abstract and claim 3. Knight utilizes such an emulsifier to reduce skin irritation. See abstract. However, an ordinarily skilled artisan would not have had any reason or rationale to substitute an emulsifier of Knight for the emulsifiers disclosed by Straub for forming the dry porous matrix of Straub because the dry porous matrix is not topically applied to skin before being reconstituted into, for example, a cream or ointment. See Straub at paragraphs [0014] and [0053]. Thus, there is no evidence that the emulsifiers of Straub would cause skin

irritation because the emulsions of Straub are not applied directly to the skin, but rather are further processed.

Thus, the applied references would not have rendered obvious claims 24, 37, and 38. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

D. Claims 25 and 27-31

The Office Action rejects claims 25 and 27-31 under 35 U.S.C. §103(a) as having been obvious over Straub, Farmer, and U.S. Patent No. 6,440,437 to Krzysik et al. ("Krzysik"). Applicants respectfully traverse the rejection.

Claims 25 and 27-31 depend from claim 21 and, therefore, contain all the features of claim 21. The deficiencies of Straub and Farmer with respect to claim 21 are discussed above. Krzysik, which the Office Action applies for the additional features recited in claims 25 and 27-31, does not cure the deficiencies of Straub and Farmer.

Additionally, Krzysik is directed to a skin health enhancing soft wet wipe or wipe-type product that can be made by combining the wipe with an oil-in-water emulsion comprising, for example, a natural fat or oil. See abstract. Applicants respectfully submit that Krzysik is nonanalogous art because it is in a different field of endeavor and is not reasonable pertinent to the problem address by the claimed subject matter because it is not directed to a galenic base that increases cell viability and reduces skin irritation.

Thus, the applied references would not have rendered obvious claims 25 and 27-31. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

E. Claim 26

The Office Action rejects claim 26 under 35 U.S.C. §103(a) as having been obvious over Straub, Farmer, and JP-A-2001-048776 to Mekideche ("Mekideche"). Applicants respectfully traverse the rejection.

Claim 26 depends from claim 21 and, therefore, contains all the features of claim 21.

The deficiencies of Straub and Farmer with respect to claim 21 are discussed above.

Mekideche, which the Office Action applies for the additional features recited in claim 26, does not cure the deficiencies of Straub and Farmer. Additionally, Mekideche does not disclose Laminaria ochroleuca as a liporegulatory substance.

Thus, the applied references would not have rendered obvious claim 26. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

III. Rejoinder

Applicants respectfully request rejoinder of non-elected claims 32 and 35. Claims 32 and 35 depend from claim 21 and, thus, should be rejoined upon allowance of claim 21 because unity of invention would exist between claims 21, 32, and 35. Applicants believe that claim 21 is allowable for at least the reasons discussed above. Accordingly, Applicants respectfully request withdrawal of the restriction requirement and rejoinder, examination, and allowance of claims 32 and 35.

IV. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of this application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachment:
Request for Continued Examination

Date: December 23, 2009

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